

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 23 FEB 2007		
FOR FURTHER ACTION See paragraph 2 below		
Applicant's or agent's file reference 110/04372		
International application No. PCT/IL05/00812	International filing date (day/month/year) 31 July 2005 (31.07.2005)	Priority date (day/month/year) 30 July 2004 (30.07.2004)
International Patent Classification (IPC) or both national classification and IPC IPC: A61F 2/44(2006.01) USPC: 623/17.11		
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 24 January 2007 (24.01.2007)	Authorized officer Paul B. Prejlic Telephone No. (571)
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL05/00812

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL05/00812

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-39, 44-49, 51 and 63

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00812

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. Citations and explanations:

Claims 1-3, 4, 6-8, 22, 23, 24, 27, 28, 30, 34, 35, 38, 39, and 44-48 lack novelty under PCT Article 33(2) as being anticipated by BAO et al (US 5,534,028) where the material is fully polymerized prior to insertion and inserting it into the body causes it to soften as it absorbs water; see Table I and column 11, lines 14-40.

Claim 63 lacks novelty under PCT Article 33(2) as being anticipated by PELLEGRINO et al (US 2003/0181963); see paragraph [0148].

Claims 1, 3, 5, 7-9, 14, 18, 27, 30, 31, 33-35, 37-39, 44-47, and 49 lack novelty under PCT Article 33(2) as being anticipated by ROSS et al (US 6,264,659); see the abstract, column 2, line 61 et seq. and column 6, line 35 et seq.

Claim 36 lacks an inventive step under PCT Article 33(3) as being obvious over ROSS et al (US 6,264,659) in view of FRONING (US 3,875,595). ROSS teaches inserting the material into the body but not the step of constraining it as claimed. However, FRONING teaches that it was known to the art to insert a prosthetic with a constraining member, such as an inflatable member, in order to constrain the inserted material; see the figures and the corresponding description thereof. Therefore, it is the Examiner's position that it would have been obvious to insert a constraining device into the vertebral area during the ROSS procedure for the same reasons that FRONING does the same or to control the shape and size of the inserted material.

Claims 10-13, 15-17, 19-21, 25, 26, 29, 32, and 51 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a Shore A hardness in the range claimed, the viscosity in the claimed range, the introduction pressure range, an extrusion aperture of 3 mm or 1.5 mm, introduction using a motor, introduction using a hydraulic source, cutting the material away from the delivery system, or accessing the space with a guidewire.

Claims 1-39, 44-49, 51, and 63 meet the criteria set out in PCT Article 33(4), and thus they possess industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE
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PCT/IL05/00812

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 10-13, 15-17, 19-21, 25, 26, 29, 32, 36, and 51
The opinion as to Novelty was negative (No) with respect to claims 1-9, 14, 18, 22-24, 27, 28, 30, 31, 33-35, 37-39, 44-49 and 63
The opinion as to Inventive Step was positive (Yes) with respect to claims 10-13, 15-17, 19-21, 25, 26, 29, 32, and 51
The opinion as to Inventive Step was negative (NO) with respect to claims 1-9, 14, 18, 22-24, 27, 28, 30, 31, 33-39, 44-49, and 63
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-39, 44-49, 51, and 63
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE